IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

ANGELA DAWN CANTRELL Plaintiff, v. COLOPLAST CORP., COLOPLAST MANUFACTURING US, LLC Defendants et al.	Case No. _____ **JURY TRIAL DEMANDED**

I. INTRODUCTION

1. Plaintiff, by her undersigned counsel, brings this Complaint against Coloplast Corporation and Coloplast Manufacturing U.S., LLC, (collectively referred to herein as "Defendants") related to the design, manufacture, marketing, distribution and sale of Defendants' Pelvic Mesh Products implanted in Plaintiff. This action is for compensatory, equitable, injunctive, and declaratory relief. Plaintiff makes the following allegations based upon her individual personal knowledge as to her own acts, and upon information and belief, as well as upon her attorneys' investigative efforts as to Defendants' actions and misconduct, and alleges as follows.

II. PARTIES

2. Plaintiff Angela Dawn Cantrell is a citizen and resident of the State of California. Plaintiff has suffered and continues to suffer significant injury as a result of Defendants' products and the conduct alleged herein.

3. Defendant Coloplast Corporation ("Coloplast Corp.") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411. Coloplast Corp. is a wholly owned U.S. sales and marketing subsidiary of Coloplast A/S.

4. Defendant Coloplast Manufacturing US, LLC is a limited liability corporation organized and existing under Delaware law, maintaining its principal place of business at 1940 Commerce Drive, North Mankato, Minnesota 56002. Its registered office is 560 Park Street, #6, St. Paul, Minnesota 55103. Coloplast Manufacturing US, LLC is a wholly owned subsidiary of Coloplast Corp. Coloplast Corp., and Coloplast Manufacturing US, LLC are collectively referred to herein as "Coloplast."

III. JURISDICTION AND VENUE

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiff and Defendants, and the amount in controversy exceeds $75,000. Defendants are subject to in personam jurisdiction in this court, and venue is proper within this district pursuant to 28 U.S.C. § 1391, as a substantial number of the events, actions, or omissions giving rise to the Plaintiff's claims occurred in this district. At all times relevant to this matter, Defendants conducted substantial business in this district. Defendants did (and do) business within the state of Minnesota and have had substantial, continuous, and systematic contacts with the state of Minnesota, have consented to jurisdiction in the state of Minnesota, and/or committed a tort in whole or in part in the state of Minnesota, against Plaintiff herein, as more fully set forth below.

IV. FACTUAL BACKGROUND

6. At all relevant times, Defendants were in the business of developing, designing, licensing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce including, *inter alia*, within the United States and, specifically, within the

State of Minnesota, either directly or indirectly through third parties, subsidiaries or related entities, transvaginal mesh.

7. The Defendants transvaginal mesh products include those known as T-Sling-Universal Polypropylene Sling, Aris-Transobturator Sling System, Supris-Suprapubic Sling System**,** Novasilk-Synthetic Flat Mesh, Exair-Prolapse Repair System, Restorelle, Smartmesh, Omnisure, Altis Single Incision Sling, and Minitape as well as any variations of these products and any unnamed Coloplast pelvic mesh product designed and sold for similar purposes, inclusive of the instruments and procedures for implementation.

8. At all relevant times, transvaginal mesh was used to treat pelvic organ prolapse and stress urinary incontinence.

9. A pelvic organ prolapse occurs when a pelvic organ, such as a bladder, drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapses can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum. Stress urinary incontinence is a type of incontinence caused by leakage of urine during moments of physical stress. It affects 20-40% of all women.

10. Surgical mesh, including transvaginal mesh, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most transvaginal mesh is comprised of non-

absorbable synthetic polypropylene. Upon information and belief, the Transvaginal Mesh implanted in Plaintiff are comprised of a synthetic, petroleum-based mesh.

11. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in the Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh.

12. When these Pelvic Mesh Products are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

13. In 1996, the FDA cleared the first mesh product for use in the treatment of stress urinary incontinence (SUI). These products include transvaginal mesh manufactured, marketed, and distributed by Defendants. These products are approved by the FDA under the abbreviated 510k approval process.

14. On February 8, 2001, Mentor announced the purchase of Porges S.A., a subsidiary of Sanofi-Synthelabo. At the time, Porges held the leading market share for urological products

in France and held a strong position throughout Europe was one of the largest manufacturers of urological products, supplying a complete range of products including pelvic mesh products.

15. In May 2005, Mentor announced the U.S. launch of its new Aris (TM) Trans-Obturator Tape. According to Mentor's launch reports, "specifically designed to utilize Mentor's patented Trans-Obturator Technique (T.O.T.(TM)), Aris represents the newest technical achievement and advanced generation of trans-obturator slings for the treatment of stress urinary incontinence in women." "The introduction of Aris furthers Mentor's position as a pioneer of the trans-obturator method for treating stress incontinence in women," commented Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation. "We are committed to driving innovation in the field of women's health to provide better solutions for physicians and the patients they serve." Analytic Biosurgical Solutions ("ABISS") FDA registration lists its proprietary device as "Mentor Aris Trans-Obturator Tape and Surgical Kit."

16. On October 12, 2005, ABISS and Mentor entered into a number of agreements pursuant to which ABISS licensed a number of ABISS' products to Mentor, which were thereafter marketed by Mentor under its trademarks, including its Aris trademark. On June 2, 2006, Mentor sold its surgical, urological, clinical and consumer healthcare business segments to Coloplast for $461,145,398, including inter alia, Mentor's October 12, 2005 agreements with ABISS and Mentor's Aris and Novasilk Pelvic Mesh Products.

17. At all times, the product marketed and sold in the United States as "Mentor Aris Trans-Obturator Tape and Surgical Kit" was manufactured by ABISS and, at all times after October 2, 2006, the product "Mentor Aris Trans-Obturator Tape and Surgical Kit" was exclusively marketed and sold in the United States by Coloplast Corp. from its principal place of business in Minneapolis, Minnesota.

18. ABISS is registered with the FDA, Registration Number 3004756681, as the manufacturer of "Mentor Aris Trans-Obturator Tape and Surgical Kit."

19. On December 5, 2005, Mentor obtained 510(k) clearance for Mentor NovaSilk Mesh. Mentor NovaSilk Mesh is a permanent, synthetic knitted propylene mesh that is square in shape and is a sterile, single use device. The Mentor NovaSilk Mesh obtained 510(k) clearance based on substantial equivalence in material, function, performance, and design to the Gynemesh Prolene Soft (Polypropylene) Mesh cleared under 510(k) K013718 and knitted polypropylene already in use under Mentor's Aris Sling cleared under 510(k) K050148. Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation commented, "The addition of NovaSilk to Mentor's expanding portfolio of women's health products for pelvic organ prolapse or stress urinary incontinence reinforces the commitment of our urology franchise to surgeons and the patients they serve by providing high quality product offerings and customer service and support."

20. Coloplast Corp.'s annual report for 2009-2010 reported that "the majority of our acquired patents and trademarks are associated with the acquisition of Mentor's urology, business in 2006." The annual report also said that Mentor signed "a non-competition clause prohibiting Mentor (the seller) from selling urology products for the next seven years…."

21. Coloplast Corp. began marketing the Exair Prolapse Repair System in May 2009 to treat pelvic organ prolapse. This product is made of NovaSilk Mesh, precut into the necessary shape with four mesh arms extending from the main body, which are used to implant the device. This product obtained 510(k) clearance based on its substantial equivalence with Coloplast Corp.'s (formerly Mentor's) NovaSilk Mesh, and Gynecare Prolift Total Pelvic Floor Repair System cleared under pre-market notification number K071512 on May 15, 2008.

22. Coloplast A/S received 510(k) clearance for the Supris Retropubic Sling System 510(k) K111233 in June 2011, as a device substantially equivalent to the Mentor Aris Suprapubic Surgical Kit.

23. On October 29, 2010, Coloplast Corp. acquired Mpathy Medical Devices, Inc. ("Mpathy"). Mpathy was founded in 2003, with the aim of developing less invasive surgical solutions for the treatment of female stress urinary incontinence and pelvic organ prolapse. Mpathy's core product lines included Minitape® and Omnisure® for stress urinary incontinence, and the Restorelle® family for pelvic organ prolapse. Defendant Coloplast Corp. said of the acquisition that Coloplast Corp.'s market position in Surgical Urology and Female Pelvic Health would immediately strengthen based on Mpathy's product portfolio including slings, mini-slings and meshes for stress urinary incontinence and pelvic floor repair and material portfolio including Smartmesh® technology.

24. On November 5, 2012, Coloplast A/S received clearance for the Altis Single Incision Sling System (K121562) as a device substantially equivalent in performance, indications, design, and materials to Coloplast's Aris System (previously Mentor's), American Medical System's MiniArc System, and C.R. Bard Ajust Adjustable Single Sling Incision.

25. Coloplast's website describes its various products, including those for treating (i) "Pelvic Organ Prolapse" and (ii) "Stress Urinary Incontinence", including "Sling Procedures." A press release issued by Coloplast described Coloplast's new corporate headquarters at 1601 West River Road in Minneapolis and stated that "Denmark-based Coloplast… selected north Minneapolis as the new home for its North American headquarters in 2006." According to the press release the new headquarters "will include one of the company's three global Innovation Centers."

26. On July 13, 2011, the FDA issued a new warning regarding serious complications associated with transvaginal mesh, manufactured, marketed, and distributed by Defendants. In this warning, the FDA indicated that serious complications associated with the transvaginal mesh were not rare, which was a change from what the FDA reported in October 2008. The FDA had also received increased reports of complications associated with the transvaginal mesh in both pelvic organ prolapse and stress urinary incontinence cases.

27. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of transvaginal mesh products in pelvic repair procedures. In its Petition, Public Citizen warned that the transvaginal mesh should be recalled because it offers no significant benefits but exposes patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, Missouri, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

28. Defendants knew or should have known that the Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendants began marketing each of its Pelvic Mesh Products, Defendants were aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in the relevant female Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction

and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

29. On or about January 18, 2018, Plaintiff Angela Cantrell underwent a surgical procedure during which her physicians implanted Coloplast Restorelle mesh into Plaintiff, which was manufactured, marketed and distributed by Defendants.

30. The Transvaginal Mesh implanted into Plaintiff was designed, manufactured, labeled, tested, advertised, marketed, distributed, and sold by Defendants, in and from Minneapolis, Minnesota, to be used by surgeons to treat pelvic organ prolapse and stress urinary incontinence and was represented by Defendants to be an appropriate and suitable product for such purpose.

31. Plaintiff subsequently suffered complications associated with the transvaginal mesh products, including, *inter alia,* severe pain with daily activities and intercourse. Plaintiff required surgical revision of the mesh in March 2019, and again in July 2019. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), urinary dysfunction, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain. As a result of these life-altering and, in

some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of Pelvic Mesh Products.

32. In many cases, women, including Plaintiff, have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

33. As a direct and proximate result of Defendants' conduct and omissions, Plaintiff has suffered, and continues to suffer, multiple, severe and painful personal injuries, including, but not limited to, urinary incontinence, physical deformity, and the loss of the ability to perform sexually.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

34. Defendants failed to disclose a known defect and affirmatively misrepresented that Transvaginal Mesh was safe for its intended use. Further, Defendants actively concealed the true risks associated with the use of Transvaginal Mesh. Neither Plaintiff nor Plaintiff's prescribing physicians had knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of Defendants' concealment of and misrepresentations regarding the true risks associated with Transvaginal Mesh, Plaintiff could not have reasonably discovered Defendants' wrongdoing at any time prior to the commencement of this action.

35. Despite diligent investigation, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the Transvaginal

Mesh was not discovered, and through reasonable care and due diligence could not have been discovered until a date within the applicable limitations period for filing Plaintiff's claims. Plaintiff did not have actual or constructive knowledge of facts indicating to a reasonable person that she was the victim of a tort. Plaintiff was unaware of the facts upon which a cause of action rests until a date within the applicable limitations period for the filing of this action. Plaintiff's lack of knowledge was not willful, negligent or unreasonable.

36. Thus, because Defendants fraudulently concealed the defective nature of Transvaginal Mesh and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendants are estopped from relying on any statute of limitations.

V. CLAIMS FOR RELIEF

COUNT I
NEGLIGENCE

37. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

38. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertising, supplying, promoting, packaging, sale, and distribution of transvaginal mesh, including the duty to assure that the Transvaginal Mesh would not cause users to suffer unreasonable, dangerous side effects.

39. Defendants failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promoting, advertising, packaging, sale, testing, quality assurance, quality control, and distribution of the Transvaginal Mesh because Defendants knew or had reason to know that using Transvaginal Mesh created a high risk of unreasonable and dangerous side effects, including, but not limited to, severe erosion of the vaginal wall and other tissues, infection, the loss of the ability to perform sexually, death and other severe personal

injuries, which are permanent and lasting in nature, including, but not limited to, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, and any and all further medical complications, such as Plaintiff's need for life-long medical treatment and care, and fear of developing further adverse health consequences.

40. Defendants manufactured, produced, promoted, formulated, created, developed, designed, sold, and distributed transvaginal mesh without thoroughly and adequately testing them;

a. Defendants manufactured, produced, promoted, advertised, formulated, created, developed, designed, and distributed its transvaginal mesh while concealing and suppressing test results;

b. Defendants did not conduct sufficient studies and tests to determine whether its transvaginal mesh were safe for their intended use, because Defendants knew, or should have known, that its transvaginal mesh were unsafe and unfit for use by reason of the dangers to their users;

c. Defendants failed to warn Plaintiff, her physicians and her other healthcare providers, the medical and healthcare community, or the public as soon as Defendants knew, or should have known, that the dangers of the use of Transvaginal Mesh were much higher than the risk of adverse effects from other, safer alternative treatments for pelvic organ prolapse and stress urinary incontinence;

d. Defendants concealed, suppressed, failed to warn about and failed to follow up on, the adverse results of clinical testing which determined that Transvaginal Mesh had a high risk of serious and dangerous adverse health effects and consequences;

e. Defendants failed to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and, more particularly, use Transvaginal Mesh.

f. Defendants advertised and recommended the use of Transvaginal Mesh, while suppressing and concealing dangers they knew to be inherent in the use of Transvaginal Mesh;

g. Defendants represented that their Transvaginal Mesh was safe for its intended use when Defendants knew, or should have known, that their Transvaginal Mesh was unsafe for its intended use. Defendants represented that Transvaginal Mesh was just as safe as other treatments for stress urinary incontinence and pelvic organ prolapse when Defendants knew, or should have known, that Transvaginal Mesh had a high risk of serious and dangerous adverse health effects and consequences as a result of which Defendants' transvaginal mesh was not as safe as other treatments for stress urinary incontinence and pelvic organ prolapse;

h. Defendants suppressed, concealed, and omitted information concerning warnings, recommendations, and observations about Transvaginal Mesh from Plaintiff, her physicians, and her other healthcare providers and from the public, while knowing that Transvaginal Mesh is unsafe and dangerous; and

i. Defendants suppressed, concealed, omitted, and misrepresented to Plaintiff, her physicians and her other healthcare providers, the medical community, the public, the severity of the risks and the dangers inherent in the intended use of Transvaginal Mesh, as compared to other treatments for stress urinary incontinence and pelvic organ prolapse.

41. Defendants were negligent in the design, research, development, manufacture, promotion, packaging, advertising, distribution, testing, marketing, and sale of Transvaginal Mesh because:

a. Defendants failed to use due care in the design, research, manufacture, and development of its transvaginal mesh so as to avoid risks to patients of serious and dangerous adverse health effects and consequences when its transvaginal mesh was used for the treatment of stress urinary incontinence or pelvic organ prolapse;

b. Defendants failed to design and manufacture its transvaginal mesh so as to minimize the risk of serious side effects, including, but not limited to, the erosion of the vaginal wall and infections; and

c. Defendants failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance, to determine the safety of transvaginal mesh.

42. While Defendants knew, or should have known, that transvaginal mesh caused unreasonably dangerous side effects, Defendants nonetheless continued and still continue to market, manufacture, distribute, advertise, promote, and sell transvaginal mesh to consumers.

43. Defendants knew, or should have known, that consumers such as Plaintiff, into whom transvaginal mesh was implanted, would foreseeably suffer severe injuries as a result of Defendants' failure to exercise ordinary care, as set forth above.

44. Defendants' negligence was the proximate cause of the injuries, harm, and economic loss that Plaintiff has suffered and will continue to suffer in the future.

45. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions, and as the direct, foreseeable and proximate result of the implantation of Defendants'

transvaginal mesh into Plaintiff, Plaintiff was caused to suffer, did suffer and will continue to suffer from physical, emotional, economic and other injury.

COUNT II
STRICT LIABILITY: DEFECTIVE DESIGN

46. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

47. At all relevant times, Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold and distributed, Transvaginal Mesh, which was implanted into Plaintiff.

48. Defendants' transvaginal mesh was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with Defendants' transvaginal mesh without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

49. At all relevant times, Defendants' transvaginal mesh was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

50. Defendants' transvaginal mesh was defective in design and formulation in that, when it left Defendants' hands, the foreseeable risks exceeded the benefits allegedly associated with the design of transvaginal mesh.

51. Defendants' transvaginal mesh was defective in design because, when it left the Defendants' hands, it was unreasonably dangerous and also was more dangerous than the ordinary consumer would expect.

52. At all relevant times, Defendants' transvaginal mesh was in a defective condition and unsafe, and Defendants knew, or should have known, that their transvaginal mesh was defective and unsafe, especially when used in the manner instructed and provided by Defendants.

53. Defendants knew, or should have known, at all relevant times, that the transvaginal mesh was in a defective condition, and was and is inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

54. At the time that the Transvaginal Mesh devices were implanted into Plaintiff, it was being used for its intended use in a manner normally intended, namely to treat stress urinary incontinence

55. Defendants had a duty to create a product, to wit, its Transvaginal Mesh that was not unreasonably dangerous for its normal, common, intended use.

56. Defendants' Transvaginal Mesh was manufactured defectively because it left the hands of Defendants in a defective condition and was unreasonably dangerous for the intended use for which it was designed, manufactured and sold.

57. Defendants designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product, to wit, transvaginal mesh that created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are, therefore, strictly liable for the injuries and damages sustained by Plaintiff.

58. Plaintiff, her physicians and her other healthcare providers could not, by the reasonable exercise of care, have discovered the defects in this product or perceived their danger.

59. Defendants' transvaginal mesh was defective due to inadequate warnings and instructions, because Defendants knew or should have known that transvaginal mesh created a risk of serious and dangerous side effects, including, but not limited to, erosion of the vaginal wall and

other tissues, infection, permanent and substantial physical deformity, loss of the ability to perform sexually, and other serious and severe personal injuries which are permanent and lasting in nature; and Defendants failed to test adequately for or to warn of these risks.

60. Defendants' transvaginal mesh was defective due to inadequate post-marketing surveillance and warnings because Defendants knew, or should have known, the risks of serious side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and the loss of the ability to perform sexually.

61. Defendants also failed to provide adequate warning for use to consumers of transvaginal mesh, and Defendants continue improperly to advertise, to market, to label, and to promote transvaginal mesh to the public and to the medical community.

62. By reason of the foregoing, Defendants are strictly liable in tort to Plaintiff.

63. The defective design of Defendants' transvaginal mesh and Defendants' over-marketing through advertisements, together with their failure to provide adequate warnings accompanying transvaginal mesh were willful, wanton, and reckless.

64. The defects in Defendants' transvaginal mesh were substantial and contributing factors in causing Plaintiff's injuries.

65. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions, and as the direct, foreseeable and proximate result of the implantation of Defendants' transvaginal mesh into Plaintiff, Plaintiff was caused to suffer, did suffer and will continue to suffer from physical, emotional, economic and other injury.

COUNT III
STRICT LIABILITY: FAILURE TO WARN

66. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

67. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released transvaginal mesh into the stream of commerce within the State of Minnesota and elsewhere, and directly advertised and marketed within the State of Minnesota and elsewhere, transvaginal mesh to consumers or persons responsible for consumers, and, therefore, had a duty to warn of the risks associated with the use of transvaginal mesh.

68. Defendants' transvaginal mesh was under the exclusive control of Defendants and was not accompanied by adequate warnings regarding adverse side effects and complications associated with the use of transvaginal mesh, or by adequate warnings regarding the comparative severity, duration and extent of the risk of injuries associated with use of transvaginal mesh.

69. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of transvaginal mesh; no healthcare provider would have prescribed — and no consumer would have used — transvaginal mesh had the facts concerning the safety and efficacy of transvaginal mesh been made known to such healthcare providers and consumers.

70. Defendants' advertising campaign for transvaginal mesh did *not* advise either consumers or healthcare providers that transvaginal mesh presented multiple and dangerous medical risks, including erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and the loss of the ability to perform sexually.

71. Defendants failed to perform or otherwise facilitate adequate testing; such testing would have demonstrated that transvaginal mesh posed serious and potentially life-threatening side effects and complications with respect to which full and proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to healthcare providers, to the FDA, and to consumers, including Plaintiff.

72. Transvaginal mesh was defective due to inadequate post-marketing warnings and instructions because, after Defendants knew, or should have known, of the risk of serious and potentially life-threatening side effects and complications from the use of transvaginal mesh, Defendants failed to provide adequate warnings to healthcare providers or to the consuming public, including Plaintiff, and instead continued to advertise and market transvaginal mesh aggressively.

73. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT IV
BREACH OF EXPRESS WARRANTIES

74. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

75. Defendants expressly warranted that their transvaginal mesh was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

76. At the time of Defendants' aforesaid express warranties, Defendants knew or should have known, that their transvaginal mesh did not conform to these express warranties because their transvaginal mesh was not safe and had numerous serious side effects, about which Defendants did not adequately warn.

77. As a direct, foreseeable, and proximate result of Defendants' breach of their express warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

78. Plaintiff relied on Defendants' express warranties with respect to their transvaginal mesh.

79. Members of the medical community, including Plaintiff's physicians and other healthcare providers, relied upon Defendants' representations and warranties in connection with the use, recommendation, description, and implantation of transvaginal mesh.

80. Defendants breached the express warranties because their transvaginal mesh was, and is, defective and unreasonably unsafe for its intended use.

81. Defendants expressly represented to Plaintiff, her physicians and her other healthcare providers that its transvaginal mesh (i) was safe and fit for the purposes intended, (ii) was of merchantable quality, (iii) did not produce any dangerous side effects in excess of those risks associated with other treatments for pelvic organ prolapse and stress urinary incontinence, (iv) the side effects it produced were accurately reflected in the warnings, and (v) it was adequately tested and fit for its intended use.

82. Defendants knew, or should have known, that their aforesaid representations and warranties were false, misleading, and untrue because its transvaginal mesh was not safe and fit for its intended use, and caused its users serious injuries of which Defendants did not adequately warn.

83. As a direct, foreseeable and proximate result of Defendants' foregoing acts and omissions, Plaintiff was caused to suffer and did suffer serious and grievous personal injuries, including erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and the loss of the ability to perform sexually, as well as other grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such

as Plaintiff's need for life-long medical treatment and medical monitoring, and perpetual fear of developing additional adverse health consequences.

84. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT V
BREACH OF IMPLIED WARRANTIES

85. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

86. At all relevant times, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and sold transvaginal mesh to treat pelvic organ prolapse and stress urinary incontinence.

87. At the time Defendants marketed, sold, and distributed transvaginal mesh for implantation into Plaintiff, Defendants knew of the intended use of transvaginal mesh, and impliedly warranted transvaginal mesh to be of merchantable quality and safe and fit for such intended use.

88. Defendants impliedly represented and warranted to Plaintiff, her physicians and other healthcare providers, to the general public, that transvaginal mesh was safe and of merchantable quality and fit for the ordinary purpose for which transvaginal mesh was to be used.

89. Defendants' representations and warranties were false, misleading, and inaccurate because transvaginal mesh was unsafe, unreasonably dangerous, improper, not of merchantable quality and otherwise defective.

90. Plaintiff, her physicians and her other healthcare providers relied on Defendants' superior skill and judgment, as to whether transvaginal mesh was of merchantable quality and safe and fit for their intended use, and as to whether transvaginal mesh was fit for this particular use.

91. Defendants put transvaginal mesh into the stream of commerce within the State of Minnesota and elsewhere, in a defective, unsafe, and inherently dangerous condition, and transvaginal mesh was expected by Defendants to and did reach Plaintiff without substantial change in the condition in which transvaginal mesh wassold.

92. Defendants breached their implied warranty because transvaginal mesh was not fit for its intended use and purpose.

93. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions within the State of Minnesota, Plaintiff was caused to suffer, and did suffer, serious and dangerous side effects of erosion of the vaginal wall and other tissues, permanent and substantial physical deformity, and the loss of the ability to perform sexually and has undergone or will have to undergo corrective surgeries and may need further corrective surgery. Plaintiff has suffered other grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and care, medical monitoring, and perpetual fear of developing additional adverse health consequences.

94. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT VI
UNJUST ENRICHMENT

95. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

96. Defendants are, and at all times were, the manufacturer, seller, and/or supplier of transvaginal mesh.

97. Plaintiff paid for transvaginal mesh for the purpose of treating stress urinary incontinence.

98. Defendants accepted payment from Plaintiff for the purchase of transvaginal mesh.

99. Plaintiff has not received the safe and effective transvaginal mesh for which she paid. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiff, as a reasonable consumer, expected.

100. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT VII
COMMON LAW FRAUD

101. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

102. Defendants falsely and fraudulently represented to Plaintiff, her physicians and her other healthcare providers, to the medical and healthcare communities, and to the public that transvaginal mesh had been tested and had been determined to be safe and effective to treat pelvic organ prolapse and stress urinary incontinence.

103. When Defendants made their aforesaid representations Defendants knew, or should have known, that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the falsity of their representations as well as the dangers and health risks to users of transvaginal mesh, including Plaintiff.

104. Defendants made the aforesaid representations with the intent of defrauding and deceiving Plaintiff, her physicians and her other healthcare providers, the medical and healthcare communities, and the public, and to induce Plaintiff, her physicians and her other healthcare providers, the medical and healthcare communities and the public, to recommend, purchase and implant transvaginal mesh to treat pelvic organ prolapse and stress urinary incontinence, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of plaintiff and other consumers.

105. In representations to Plaintiff, her physicians and her other healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

a. Transvaginal mesh is not as safe as other forms of treatment for pelvic organ prolapse and stress urinary incontinence;

b. The risk of adverse events with transvaginal mesh was not adequately tested and was known by Defendants;

c. Defendants deliberately failed to follow up on the adverse results from clinical studies and buried and misrepresented those results;

d. Defendants were aware at all times of the dangers in transvaginal mesh, in addition to, and above and beyond the risks normally associated with treating pelvic organ prolapse and stress urinary incontinence;

e. Transvaginal mesh was defective, and caused dangerous and adverse side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and loss of the ability to perform sexually, at a much more significant rate than other treatments for pelvic organ prolapse and stress urinary incontinence;

f. Patients with transvaginal mesh implanted need to be monitored more regularly than patients treated with other treatments for pelvic organ prolapse and stress urinary incontinence;

g. Transvaginal mesh was manufactured negligently;

h. Transvaginal mesh was manufactured defectively; and

i. Transvaginal mesh was designed negligently and defectively.

106. Defendants had a duty to disclose to Plaintiff, her physicians and her other healthcare providers, the defective nature of transvaginal mesh, including, but not limited to, the fact that transvaginal mesh had heightened risks of dangerous side effects.

107. Defendants had sole access to the facts concerning the defective nature of transvaginal mesh and its propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons into whom transvaginal mesh was implanted, including Plaintiff.

108. Defendants' aforesaid concealment and omissions of material fact concerning the safety of transvaginal mesh were made intentionally, willfully, wantonly, and recklessly to

mislead, to cause Plaintiff's physicians and her other healthcare providers to purchase and to implant transvaginal mesh, and to mislead Plaintiff into reliance and to cause Plaintiff to permit transvaginal mesh to be implanted into her.

109. At the time that Defendants made these representations, and at the time transvaginal mesh was implanted into Plaintiff, Plaintiff was unaware of the falsehood of Defendants' aforesaid representations, reasonably believed them to be true, and relied upon them.

110. Defendants knew, or should have known that transvaginal mesh could and would cause severe and grievous personal injury to women into whom they were implanted and that transvaginal mesh was inherently dangerous in a manner that exceeded any purported benefit from the use of transvaginal mesh and any warnings gave concerning transvaginal mesh.

111. In reliance upon Defendants' false representations, Plaintiff was induced to, and did permit transvaginal mesh to be implanted into her, thereby sustaining severe and permanent personal injuries and damages. Defendants knew, or should have known, that Plaintiff, her physicians and her other healthcare providers had no way to determine that Defendants concealed and omitted facts necessary to make the statements Defendants made about transvaginal mesh true.

112. Plaintiff, her physicians and her other healthcare providers reasonably relied on Defendants' statements and representations which suppressed and concealed facts that were critical to understanding the dangers inherent in the use of transvaginal mesh.

113. As a result of Defendants' research, clinical trials, testing or lack thereof, Defendants intentionally distributed false information and made false statements and representations, including, but not limited to, assuring Plaintiff, her physicians, and her other healthcare providers and the public that transvaginal mesh was safe to treat pelvic organ prolapse and stress urinary incontinence. Defendants intentionally omitted, concealed and suppressed the

results of their research, clinical trials and testing from Plaintiff, her physicians and her other healthcare providers and the public.

114. Defendants had a duty when disseminating information to the public, including Plaintiff, to disseminate truthful information; and Defendants had a parallel duty not to deceive the public, Plaintiff, Plaintiff's physicians and Plaintiff's other healthcare providers.

115. The information Defendants distributed to Plaintiff, her physicians, and her other healthcare providers, to the public, and to the medical community, included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing representations, which were materially false and misleading, and which contained material omissions of the truth about the dangers of the use of transvaginal mesh.

116. Defendants misrepresented to Plaintiff, her physicians and her other healthcare providers, to the healthcare and medical communities, and to the public, the material facts that transvaginal mesh did not have dangerous or serious adverse health safety concerns, and that transvaginal mesh was as safe as other means of the treatment of pelvic organ prolapse and stress urinary incontinence.

117. Defendants' intent in making these misrepresentations was to deceive and defraud and to gain the confidence of Plaintiff, her physicians and her other healthcare providers, the medical community, and the public and to induce Plaintiff, her physicians and her other healthcare providers, the healthcare and medical communities, and the public to request, recommend, and implant transvaginal mesh into patients, including Plaintiff.

118. Defendants made claims and representations in reports to the public and to healthcare professionals and in advertisements that transvaginal mesh did not present serious health risks.

119. Defendants' aforesaid representations were knowingly false when made or were made recklessly and without regard to the true facts.

120. Defendants' aforesaid representations were made with the intention of deceiving and defrauding Plaintiff, her physicians and her other healthcare providers and other members of the healthcare and medical communities, were made in order to induce Plaintiff, her physicians and her other healthcare providers to dispense, recommend, and implant transvaginal mesh into Plaintiff.

121. Defendants intentionally concealed, omitted and misrepresented the dangerous and serious health and safety concerns inherent in the use of transvaginal mesh for the purpose of influencing the sales of a product known to Defendants to be dangerous and defective, and certainly not as safe as other alternatives for treating pelvic organ prolapse and stress urinary incontinence.

122. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving Plaintiff, her physicians and her other healthcare providers, into a false sense of security, to induce Plaintiff's physicians and other healthcare providers to recommend, dispense, and implant transvaginal mesh into Plaintiff, and to induce Plaintiff to permit transvaginal mesh to be implanted into her.

123. Plaintiff and her healthcare providers relied to their detriment on Defendants' misrepresentations and omissions. Had Plaintiff known the truth about the dangers and serious

health and safety risks of transvaginal mesh, Plaintiff would not have permitted transvaginal mesh to be implanted into her.

124. Defendants' fraud and deceit was perpetrated willfully, wantonly, and purposefully on Plaintiff.

125. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions Plaintiff was caused to suffer, and did suffer, the serious and dangerous side effects of erosion of the vaginal wall and other tissues, permanent and substantial physical deformity and loss of the ability to perform sexually, has undergone corrective surgeries and will likely require further corrective surgery, and suffered further grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and care, medical monitoring and perpetual fear of developing additional adverse health consequences.

126. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT VIII
NEGLIGENT MISREPRESENTATION

127. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

128. Defendants had the duty to accurately and truthfully represent to the medical and healthcare communities, to Plaintiff, her physicians and her other healthcare providers, and to the public, that transvaginal mesh had been tested and had been determined to be safe and effective

for treating pelvic organ prolapse and stress urinary incontinence. Defendants' representations of safety and effectiveness of transvaginal mesh were false.

129. Defendants failed to exercise ordinary care in their representations concerning transvaginal mesh because Defendants negligently concealed, omitted and misrepresented transvaginal mesh' high risk of unreasonable, dangerous, adverse side effects.

130. Defendants knew, or should have known, that transvaginal mesh had been insufficiently tested, or had not been tested at all, lacked adequate and accurate warnings, and created a high risk, or higher than acceptable risk, or higher than reported and represented risk, of adverse side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and loss of the ability to perform sexually.

131. As a direct, foreseeable and proximate result of Defendants' wrongful acts and omissions, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT IX
VIOLATION OF APPLICABLE STATE CONSUMER FRAUD & DECEPTIVE TRADE PRACTICES LAWS

132. Plaintiff re-alleges the allegations contained in the foregoing paragraphs.

133. Defendants have a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of the defective products.

134. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the defective product referenced herein, and would not have incurred related medical costs and injury.

135. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for the defective product that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

136. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the defective product. Each aspect of Defendants' conduct combined to artificially create sales of the defective product.

137. Defendants are liable to Plaintiff jointly and severally for all general, special and injunctive relief to which Plaintiff is entitled by law. Under statutes enacted in Minnesota and California to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Plaintiff is a consumer who purchased Defendants' pelvic mesh product pursuant to a consumer transaction for personal use and is therefore subject to protection under such legislation.

138. Under statutes enacted in Minnesota and California to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendant is the supplier, manufacturer, advertiser, and seller, who is subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

139. Defendants violated the statutes enacted in Minnesota and California to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Pelvic Mesh product was fit to be used for the purpose for which it was intended, when in fact the Pelvic Mesh product was defective and dangerous.

140. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in Minnesota and California to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

141. Defendants had actual knowledge of the defective and dangerous condition of the Pelvic Mesh product, and failed to take any action to cure such defective and dangerous conditions.

142. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which Pelvic Mesh product and/or produce to utilize.

143. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and practices in violation of Minn. Stat. §§ 325D.43, et seq., 325F.67, et seq., 325F.68 et seq. and West's Ann.Cal.Civ.Code § 1750, et. seq.

144. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable loss and damages.

145. As a direct and proximate result of Defendants' violations of Minn. Stat. §§ 325D.43, et seq., 325F.67, et seq., 325F.68, and Cal. Civ. Code § 1750, et. seq. Plaintiff has sustained economic losses and other damages and is entitled to statutory, compensatory, injunctive and declaratory relief in an amount to be proven at trial.

COUNT X
VIOLATION OF MINNESOTA FALSE STATEMENTS IN ADVERTISING ACT

146. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

147. Defendants produced and published advertisements and deceptive and misleading statements of the soundness and mechanical reliability of the Pelvic Mesh product after learning of their inherent defects with the intent to sell the Pelvic Mesh product.

148. Defendants concealed their deceptive practices in order to increase the sale of and profit from the Pelvic Mesh product.

149. Defendants violated the Minnesota False Statements in Advertising Act, Minn. Stat. § 325F.67 et seq., when they failed to comply with FDA requirements and when they failed to adequately warn consumers and the medical community of the safety risks associated with the Pelvic Mesh products.

150. Defendants violated Minn. Stat. § 325F.67 by intending to sell and create customer demand for the Pelvic Mesh products by using deceptive or untrue statements of fact about the Pelvic Mesh products mechanical soundness, efficacy, safety, and the reliability of the Pelvic Mesh product through promotional materials, including but not limited to, Defendants' website and medical brochures distributed to patients and physicians.

151. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct and violation of Minn. Stat. § 325F.67 et seq., Plaintiff was injured in that they paid substantial sums for the Pelvic Mesh product and for the costs of treating associated injuries and revising the Pelvic Mesh product that she would not have paid had Defendants not engaged in unfair and deceptive conduct.

152. The Minnesota False Statement in Advertising Act applies to Plaintiff's transactions with Defendants because Defendants deceptive scheme was carried out in Minnesota and affected Plaintiff implanted with the defective Pelvic Mesh product.

153. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has also sustained and will continue to sustain severe physical injuries, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory, injunctive, equitable, and declaratory relief in an amount to be proven at trial.

COUNT XI
VIOLATION OF THE MINNESOTA PREVENTION OF CONSUMER FRAUD ACT

154. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

155. Defendants produced and published advertisements and deceptive and misleading statements of the soundness and mechanical reliability of the Pelvic Mesh product after learning of their inherent defects with the intent to sell the Pelvic Mesh product.

156. Defendants concealed their deceptive practices in order to increase the sale of and profit from the Pelvic Mesh product.

157. Defendants violated the Minnesota False Statements in Advertising Act, Minn. Stat. § 325F.67 et seq., when they failed to comply with FDA requirements and when they failed to adequately warn consumers and the medical community of the safety risks associated with the Pelvic Mesh products.

158. Defendants violated Minn. Stat. § 325F.67 by intending to sell and create customer demand for the Pelvic Mesh products by using deceptive or untrue statements of fact about the Pelvic Mesh products mechanical soundness, efficacy, safety, and the reliability of the Pelvic Mesh product through promotional materials, including but not limited to, Defendants' website and medical brochures distributed to patients and physicians.

159. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct and violation of Minn. Stat. § 325F.67 et seq., Plaintiff was injured in that they paid substantial sums for the Pelvic Mesh product and for the costs of treating associated injuries and revising the Pelvic Mesh product that she would not have paid had Defendants not engaged in unfair and deceptive conduct.

160. The Minnesota False Statement in Advertising Act applies to Plaintiff's transactions with Defendants because Defendants deceptive scheme was carried out in Minnesota and affected Plaintiff implanted with the defective Pelvic Mesh product.

161. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has also sustained and will continue to sustain severe physical injuries, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory, injunctive, equitable, and declaratory relief in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages according to proof and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present;

2. Special damages according to proof and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including, permanent instability and loss of balance, and pain and suffering;

3. All other damages as allowed by law;

4. Disgorgement of profits; and

5. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands a jury trial on all claims so triable in this action.

Dated: March 5, 2020.

RESPECTFULLY SUBMITTED,

GOLDENBERG LAW, PLLC

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